

Drug Utilization Review Board
Meeting Minutes, Open Session, April 10, 2019

Drug Utilization Review Board

Meeting Location: DXC Technology,
 Building #283, Capital Room 6511
 SE Forbes Ave, Topeka, KS 66619

DUR Board Members:

James Backes, PharmD (Interim Chair)
 Jennifer Clair, MD
 Katie Burenheide Foster, PharmD, MS, BCPS, FCCM
 Moneeshindra Mittal, MD (Phone)
 LaTonya Rice, PharmD, CGP
 Serena Stutzman, APRN (Absent)
 Roger Unruh, DO

KDHE/DHCF/Contractor Staff:

Annette Grant, RPh.
 Victor Nguyen, PharmD
 Margaret O'Donnell, Transcriptionist

DXC Technology Staff:

Karen Kluczykowski, RPh.
 Kathy Kaesewurm, RN, BSN

HID Staff:

Taylor DeRuiter, PharmD
 Ariane Casey, PharmD

MCO Staff:

Jennifer Murff, RPh, UnitedHealthcare Community Plan
 Alan Carter, PharmD, Aetna Better Health of Kansas
 Angie Zhou, PharmD, Sunflower State Health Plan (Absent)

Public Attendees:

Jim Baumann, Rob Hansen, Phil King, Pfizer; Lesa Castillo, Kelly Burns, Aetna; Jeff Knappen, Spark; Donna Osterlund, SGZ; Marla Wiedermann, Novo Nordisk; Rick Kegler, Jeff Mussack, Otsuka; Corey Ridge, UNML; Mary MacPharrin, Mike Donze, Garth Wright, Genentech; Maggie Murphy, A. Zimmerman, Deron Grothe, Teva; Bret Hildebrand, Marcos Valdez, Gilead; Trina Ballard, Lori Howarty, Bayer

*Illegible names on the sign-in sheet were not included.

TOPIC	DISCUSSION	DECISION
I. Call to Order	Dr. Backes called the meeting to order at 10:01 a.m. (Quorum met)	
II. Old Business A. Review and approval of January 9, 2019 Meeting Minutes	<u>Board Discussion:</u> None.	Dr. Unruh moved to accept the minutes as written. Dr. Foster seconded the motion. The motion was approved unanimously.
III. New Business A. New Preferred Drug List (PDL) Class 1. CGRP Receptor Antagonists	<u>Background:</u> At the March 2019 PDL meeting, the committee approved the addition of CGRP Antagonists to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. <u>Public Comment:</u> Maggie Murphy with Teva spoke on behalf of Ajovy®. <u>Board Discussion:</u> None.	Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
2. Corticosteroids - Ophthalmic	<u>Background:</u> At the March 2019 PDL meeting, the committee approved the addition of Ophthalmic Corticosteroids to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. <u>Public Comment:</u> None. <u>Board Discussion:</u> None.	Dr. Foster moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION
A. New Preferred Drug List (PDL) Class (Continued) 3. Leukotriene Modifiers	<p><u>Background:</u> At the March 2019 PDL meeting, the committee approved the addition of Leukotriene Modifiers to the PDL. Standard non-preferred prior authorization criteria authorization criteria are being proposed for this new class to allow access to non-preferred agents.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> None.</p>	Dr. Unruh moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 1. Non-Preferred PDL PA Criteria	<p><u>Background:</u> The Non-preferred PDL PA criteria were last updated in July 2018. This revision includes adding criteria for utilization of inhaled products in nebulized dosage forms.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> The State shared that this was to open up access for those with low FEV, etc., in which the need was revealed by a recent FFS PA request.</p>	Dr. Foster moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
2. Advanced Medical Hold Manual Review (AMHMR) PA	<p><u>Background:</u> The AMHMR PA criteria functions as a pre-approval management process for new-to-market drugs or new formulations thereof, until the DUR Board can give a full review regarding permanent PA criteria. The AMHMR PA was approved in October 2018 and is being revised to extend the time period to allow for data review before making a request for permanent PA.</p> <p><u>Public Comment:</u> None.</p>	

TOPIC	DISCUSSION	DECISION
B. Revised Prior Authorization (PA) Criteria (Continued) 2. Advanced Medical Hold Manual Review (AMHMR) PA (Continued)	<p><u>Board Discussion:</u> The State stated that the current time frame of 180 days is not long enough to determine best permanent PA management. Some drugs were approved before October 2018, but just now available on the market and that some drugs would only have the standard Medical Hold designation as a pre-management option, which the current AMHMR PA does not have listed as an option</p>	<p>Dr. Rice moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.</p>
3. Anti-Emetics: Neurokinin 1 (NK-1) Antagonists/NK-1 Antagonist Combinations	<p><u>Background:</u> The prior authorization criteria were first approved in April 2018 and are being revised to include the intravenous formulation of Akynzeo® (fosnetupitant/palonosetron) to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> None.</p>	<p>Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.</p>
4. Hepatitis C Agents	<p><u>Background:</u> The criteria and transition to a class PA were initially approved in July 2018. This revision includes removal of the provider specialty requirement and changes to the patient education and adherence criterion.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> The State said that articles from specialists believe that with the simplified regimen and advanced treatment options that non-specialists should be allowed to treat patients with Hep-C. This will also improve access and hopefully adherence for patients to have more/local providers available.</p>	<p>Dr. Unruh moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.</p>

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<p>B. Revised Prior Authorization (PA) Criteria (Continued)</p> <p>5. Long-Acting Hemophilia Factors</p>	<p><u>Background:</u> Long-acting hemophilia agents are indicated for the treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding. The prior authorization criteria were initially approved in July 2017. The revision includes addition of Jivi® and Esperoct® to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.</p> <p><u>Public Comment:</u> Trina Ballard with Bayer yielded her time back to the Board with the offer to answer any questions they may have concerning Jivi®.</p> <p><u>Board Discussion:</u> None.</p>	<p>Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.</p>
<p>6. Opioid Products Indicated for Pain Management</p>	<p><u>Background:</u> These criteria cover all short and long-acting opioids. This PA was last reviewed in October 2018. The prior authorization criteria are being revised to update the benzhydrocodone conversion factor, to address the chronic pain use renewal criteria, and to ensure appropriate use.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> A Board member asked if the State had any information on the Demerol numbers. The state did not, but that Demerol is a non-preferred PDL drug due to the PDL Committee's recommendation that it not be promoted as an analgesic and references regarding its limited use.</p>	<p>Dr. Clair moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.</p>

TOPIC	DISCUSSION	DECISION
<p>C. New Prior Authorization (PA) Criteria</p> <p>1. Calcimimetic Agents</p>	<p><u>Background:</u> Calcimimetics are medications used in the treatment of hyperparathyroidism as they mimic the action of calcium on tissues on calcium receptors to lower parathyroid hormone secretion without having to raise a patient's serum calcium levels. These criteria utilize the previously approved criteria for Sensipar® to create a new class PA that includes Parsabiv® for the purpose of consolidation, as well as to ensure appropriate use.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> The Board asked for utilization of these agents. Data showed that there were 59 patients in the prior year who took Sensipar®. The State said they looked to other states management & this supported the State's decision to proceed with the proposed PA.</p>	<p>Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.</p>
<p>C. New Prior Authorization (PA) Criteria</p> <p>2. Hemlibra®</p>	<p><u>Background:</u> Hemlibra® is a humanized bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.</p> <p><u>Public Comment:</u> Mike Donze with Genentech spoke on behalf of Hemlibra® and patient provider choice.</p> <p><u>Board Discussion:</u> The discussion revolved around saving this drug for patients that had developed inhibitors to other hemophilia Factor VIII agents. There are many benefits to this drug and so additional information is needed before a decision could be made. The State and the Board determined that it would be best to table this PA, until further information can be gathered.</p>	<p>Dr. Foster moved to table the agenda item to the July DUR Meeting. Dr. Clair seconded the motion. The motion was approved unanimously.</p>

TOPIC	DISCUSSION	DECISION
C. New Prior Authorization (PA) Criteria 3. Interleukin-5 (IL-5) Receptor Antagonist Agents	<p><u>Background:</u> These criteria will combine and supersede all previous criteria for interleukin-5 (IL-5) receptor antagonist agents. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> None.</p>	<p>Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.</p>
4. Topiramate Extended Release	<p><u>Background:</u> These criteria will combine and supersede all previous criteria for Topiramate ER agents. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to ensure cost effective use.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> The Board asked if cost is the reason this is not an option before Botox. The State provided data showing the annual per patient cost of Botox is around \$5,200 and that Topiramate ER is around \$8,000.</p>	<p>Dr. Clair moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.</p>
5. PDL Expanded Consent Agenda Item	<p><u>Background:</u> At the March 2019 PDL meeting, the PDL Committee approved to expand the Consent Agenda Item criteria, which would allow pre-approval of drugs to the PDL based upon the following: a) if the new drug is a racemic mixture, a single enantiomer, diastereomer, or isomer of a current PDL drug, or b) the new drug is a prodrug of a current PDL drug, or c) the new drug includes the active ingredient moiety of a current PDL drug in the same PDL class/category but differs by brand name or manufacturer.</p> <p><u>Public Comment:</u> None.</p> <p><u>Board Discussion:</u> None.</p>	<p>Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.</p>

TOPIC	DISCUSSION	DECISION
<p>D. Mental Health Medication Advisory Committee (MHMAC)</p> <p>1. Antipsychotic Medications – Safe Use for All Ages</p>	<p><u>Background:</u> At the February 2019 MHMAC meeting, the committee revised the criteria for use of antipsychotic agents. The criteria were last reviewed in October 2018 and have been revised to include the agent Abilify MyCite®.</p> <p><u>Public Comment:</u> Rick Kegler with Otsuka spoke on behalf of Abilify MyCite®.</p> <p><u>Board Discussion:</u> Ms. Grant provided the Board with some background on Abilify MyCite®. There was some discussion about it being too cost prohibitive. Ms. Grant summarized some feedback from psychiatrists on the MHMAC Committee concerning Abilify MyCite®. There was discussion about approving this agenda item as is or sending it back to the MHMAC Committee. There was some discussion about the documented tolerance wording. Wordsmithing was requested for the next MHMAC meeting.</p>	<p>Dr. Clair moved to approve. Dr. Foster seconded the motion with the request for wordsmithing at the next MHMAC meeting. The motion was approved unanimously.</p>
<p>E. Miscellaneous Items</p> <p>1. Management of Medications Not Addressed in Their Associated Class PA</p>	<p>There are areas of clinical concern which will be monitored via non-prior authorization methods.</p> <p>R-DUR management method:</p> <ol style="list-style-type: none"> 1. Patients on Mirtazapine and/or Trazodone monitored for multiple concurrent use with other antidepressants on that PA. 2. Patients ≥65 years old, not in an LTC, with dementia, and on an antipsychotic without proper diagnosis. (Peer to Peer consult will be required.) 3. Patients exceeding the concurrent use of four or more mood stabilizers for greater than 60 days. <p>Soft-edit at the Point-of-Sale management method:</p> <ol style="list-style-type: none"> 1. Patient concurrent use of opioids and benzodiazepines under the care of more than one provider. 2. Patient concurrent use of opioids and antipsychotic use under the care of more than one provider. <p>Exact management of these 5 scenarios will be determined by State policy but will not be PA criteria at this time.</p>	<p>No motions needed. State update to the DUR Board only.</p>

IV. Open Public Comment	None.	
V. Adjourn	The meeting adjourned at 11:49 a.m.	Dr. Foster moved to adjourn. Dr. Rice seconded the motion. The motion to adjourn was approved unanimously.

The next DUR Board meeting is scheduled for July 10, 2019.

All approved PA criteria are posted to the KDHE website- http://www.kdheks.gov/hcf/pharmacy/pa_criteria.htm